EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas DiMauro on 9/20/2010.

The application has been amended as follows:

Please use the following version of claims:

Claim 1. A method of treating spinal disc defects comprising the steps of

a) preparing a disc treatment site;

b) selecting a disc defect repair material comprising small intestinal submucosa (SIS) in the form of a strip having a length, a width, and a thickness, wherein the thickness is at least one order of magnitude lower than either the width or the length; and

c) inserting the repair material in a twisting manner into the disc treatment site to be repaired to form a mushroom shape.

Claims 2-16. (cancelled)

Claim 17. The method of ~~any one of claims 1, 4-7, 14, and 16,~~ claim 1, wherein the repair material is cell seeded.

Claim 18. The method of claim 17, wherein the cells are selected from the group consisting of stem cells, bone marrow cells, fibrocytes, adipocytes, chondrocytes, cells harvested from spinal discs in the body, ~~such as~~ nucleus pulposus cells, [[and]] annulus fibrosis cells, and combinations thereof.

Claim 19. The method of claim 18, wherein the cells are stem cells.

Claim 20. The method of any one of claims 1, and 17-19[[~~4~~-7, and 14-16,]] wherein the repair material is combined with an autologous medium prior to ~~implantation~~ step c) inserting.

Claim 21. The method of ~~any one of claims 1, 4-7, 14, and 16,~~ claim 20, wherein the ~~material is combined with an~~ autologous medium is selected from the group consisting of platelet-rich plasma, platelet-poor plasma, bone marrow, whole blood and serum.

Claim 22. The method of claim [[20]]21, wherein the autologous medium is bone marrow.

Claim 23. The method of any one of claims 1, and 17-19, [[4-7, and 14-16]]wherein the repair material further comprises a bioactive factor.

Claim 24. The method of claim 23, wherein[[,]] the bioactive agent is selected from the group consisting of members of the Transforming Growth Factor-beta (TGF-ß) gene superfamily~~and agents in the same family of growth factors~~, platelet-derived growth factors, fibroblast growth factors, insulin-like growth factors, ~~protein polymers such as~~ RGD-peptides, [[and]] Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

Claim 25. The method of claim 24, wherein the bioactive factor is a Transforming Growth Factor-beta gene superfamily member selected from the group consisting of TGF-ß1, TGF-ß2, [[and]] TGF-ß3, GDF-5, MP52, and BMPs.

Claims 26-31. (cancelled)

Claim 32. The method of claim 20, wherein the repair material further comprises a bioactive factor.

Claim 33. The method of claim 32, wherein the bioactive agent is selected from the group consisting of members of the Transforming Growth Factor-beta (TGF-ß) gene superfamily ~~and agents in the same family of growth factors~~, platelet-derived growth factors, fibroblast growth factors, insulin-like growth factors, ~~protein polymers such as~~ RGD-peptides, [[and]] Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

Claim 34. The method of claim 33, wherein the bioactive factor is a Transforming Growth Factor-beta gene superfamily member selected from the group consisting of TGF-ß1, TGF-ß2, [[and]] TGF-ß3, GDF-5, MP52, and BMPs.

Claim 35. The method of claim 21, wherein the repair material further comprises a bioactive factor.

Claim 36. The method of claim 35, wherein the bioactive agent is selected from the group consisting of members of the Transforming Growth Factor-beta (TGF-ß) gene superfamily ~~and agents in the same family of growth factors~~, platelet-derived growth factors, fibroblast growth factors, insulin-like growth

factors, ~~protein polymers such as~~ RGD-peptides, [[and]] Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

Claim 37. The method of claim 36, wherein the bioactive factor is a Transforming Growth Factor-beta gene superfamily member selected from the group consisting of TGF-ß1, TGF-ß2, [[and]] TGF-ß3, GDF-5, MP52, and BMPs.

Claim 38. The method of claim 22, wherein the repair material further comprises a bioactive factor.

Claim 39. The method of claim 38, wherein the bioactive agent is selected from the group consisting of members of the Transforming Growth Factor-beta (TGF-ß) gene superfamily~~and agents in the same family of growth factors~~, platelet-derived growth factors, fibroblast growth factors, insulin-like growth factors, ~~protein polymers such as~~ RGD-peptides, [[and]] Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

Claim 40. The method of claim 39, wherein the bioactive factor is a Transforming Growth Factor-beta gene superfamily member selected from the group consisting of TGF-ß1, TGF-ß2, [[and]] TGF-ß3, GDF-5, MP52, and BMPs.

Claim 41. (cancelled)

Examiner's Reasons for Allowance

The following is a statement of the Examiner's reasons for allowance:

The claims, in the allowed state, are limited to a method wherein the spinal disc repair material must be small intestinal submucosa (SIS) which is initially provided in a strip form, and then is implanted in a manner involving twisting of the strip such that the material ultimately forms a mushroom-like shape only upon implantation. Plouhar et al (US 2001/0023373), herein made of record, is considered to be the closest prior art, in that they teach use of SIS to repair spinal disc defects; however, Plouhar et al is distinct from the method of the instant claims in that Plouhar et al combines multiple strips of SIS to form a significantly three-dimensional construct and then carving the desired implant shape out of the three-dimensional construct prior to implantation (ex vivo) (See Plouhar et al, ¶0033-0053), only after a construct having the desired shape is formed, is the construct implanted. Prior art previously relied upon, including Gan et al and Bilbo similarly taught shaping the implant material prior to insertion into the defect site, which is distinct from the instant method, which requires the shaping to be achieved by the actual insertion technique.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are of informal quality for publication. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application See MPEP 1302.05

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651